



2. Scope of regulation

The Australian Government is improving access to agricultural chemicals and veterinary medicines (agvet chemicals) as part of the Agricultural Competitiveness White Paper. Our plan to build a stronger, more prosperous agricultural sector and economy.

This paper seeks your views on one proposed reform to the agvet chemicals system—changes to better align the assessment a chemical product gets when it is registered with the risk of using the product. The proposal supports the work of the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the University of Melbourne’s Centre of Excellence for Biosecurity Risk Analysis (CEBRA).

This paper will be used as a basis for discussion at workshops to be held in Canberra, Perth, Brisbane, Sydney and Melbourne from 27 October to 13 November 2015. If you are unable to attend these workshops and would like to provide feedback on the reforms, please email agvetreform@agriculture.gov.au by 30 November 2015.

Opportunity

The APVMA should regulate products according to risk where it is the best placed regulator for the job. Reviewing the scope of products regulated by the APVMA and revising the methods the APVMA uses for regulating access to the market may allow the costs of regulating these products to be reduced.

Regulation pathways

Currently there are five pathways for prospective suppliers of agvet chemical to access the market for these products. The degree of regulatory ‘touch’ generally increases with each pathway, as does the cost of regulation. The current pathways include the ‘normal’ registration process, registration of listed chemical products, reservation and exclusion.

Different regulation pathways allow for the regulatory burden associated with each pathway to match the risks posed by the product. The registration process is the most frequently used pathway. Little use has been made of the other pathways; in the last decade:

- five classes of products have been excluded from being considered agvet chemical products
- no products have been added to the reserved list; and
- only two standards for listed chemical products have been made, one of which has been used infrequently. Most of these products are registered via the normal registration pathway.

It may be possible to revise the current regulatory pathways, or include new pathways, like the self-registration of listed products or conditional or provisional registration. The goal of this process would be to improve the efficiency of the APVMA’s processes and better match the risk a product poses with the cost and burden of regulation.

Regulation scope

The APVMA currently regulates products that pose similar risks to products managed by other competent Australian regulators. For example, the APVMA regulates some general sanitiser products (including some pool chemicals) while other products used in the home that pose similar risks (like drain cleaners) are managed under other regulatory schemes. Some of the products the APVMA regulates have characteristics more in common with cosmetics, personal hygiene products and other consumer goods.

It may be more appropriate for some classes of products to fall under different regulatory arrangements as those arrangements may better suit the risks posed by the products.

What we have heard

We have heard that the chemicals and user industry groups strongly support regulating chemicals according to risk and strongly support having the APVMA focus its skill in regulation on products that pose the greatest risks. Stakeholders support an approach that embraces the work the APVMA is doing to revise its risk assessment framework as part of this reform approach.

On regulation pathways, we have heard about some of the shortcomings of the existing approach to listed chemical registration. Industry and government stakeholders told us that the process for development of a standard for listed chemical products, including the consultation protocol, is too cumbersome and resource intensive for both the APVMA and the affected industry sectors. Concern was also expressed by some stakeholders that an increased APVMA focus on development of standards for listed products would detract from APVMA efforts on higher risk matters, contrary to the stated goal of aligning regulatory effort with risk.

Chemical manufacturing stakeholders and some producers noted the value a provisional registration pathway provides international regulators and that similar flexibility should exist within the Australian system. Provisional registrations (also called conditional registrations) allow a limited access to the market for products lacking information to address the statutory criteria completely. The access is conditional on the presentation, and acceptability, of the information at a later date. The market access allows some of the costs of the information generation to be offset.

On regulation scope, chemicals industry stakeholders from the segments of the chemicals market that includes consumer goods and home and garden products strongly support revising the range of products regulated by the APVMA. Other chemicals industry businesses are concerned at having their products regulated under regulatory frameworks that are less efficient or more burdensome than exists currently. Some farm industry stakeholders do not support rationalising the range of products regulated by the APVMA. These stakeholders consider the APVMA would be the most appropriate agency to manage the risk posed by, for example, sanitisers and disinfectants used in agriculture, even though these products may not be specific to agriculture.

The proposed reform measure

The APVMA has engaged CEBRA to develop a risk framework to more transparently align the level of assessment with the risk of the product. Preliminary findings have noted that other regulatory regimes (such as therapeutic goods) offer a self-assessment pathway for some products. In the existing agvet chemical arrangement, self-registration could effectively operate between the existing reserved and listed chemical product approaches.

This proposal would seek to support the work of the APVMA and CEBRA and be developed in two parts. In the short term, the measure would seek to simplify existing arrangements to improve the efficiency and increase their attractiveness to industry and the APVMA, and to introduce approaches for allowing for self-registration and provisional registration. Self-registration would be similar in approach to listed registration but incorporate standards where self-determination of compliance was straightforward and the risks posed by the product do not warrant direct regulatory engagement prior to market access. Some stakeholders favour a provisional registration model that bridges the space between permit and registration and adopts some of the features of international models. An analogy of provisional registrations would be provisional driving licences.

The second part of the proposal would occur over the longer term. It would identify classes of products suitable for lower regulatory oversight and develop the standards or prescribed conditions allowing access to the appropriate regulatory approach. Products where the risks are relatively uniform or where a high degree of chemical similarity exists could be suitable for standardised approaches to risk management. These could include:

- companion animal health preventative care products, personal insect repellents, and pesticides for ornamental plants
- household insecticides and hard surface disinfectants.

Other classes of products, such as whole viable seeds, may best suited to exclusion from regulation as an agvet chemical.

Next steps

We have been encouraged by stakeholder input on this measure to date and believe it is a reform that could be delivered in the early stages of the wider reform package.

We will be hosting a series of workshops for all interested stakeholders to attend and provide their views on the proposed reform measures. To attend one of these workshops please fill in a [registration form](#).

If you are unable to attend one of the workshops or would like to provide feedback separately, contact the department via email at agvetreform@agriculture.gov.au.

When providing your feedback you might like to consider addressing the following questions:

- Do you support the proposed reform in its current form or would you like further detail?
- If you don't support it, could the reform be amended to achieve your support? If so how?
- Are there any unintended consequences arising from this reform?
- Does the proposed reform result in new issues for you?

Please provide your feedback by 30 November 2015 so we can consider it before finalising a policy paper outlining a comprehensive reform package. The final policy paper will be released for stakeholder comment in the first quarter of 2016.